

Notice of Allowability

Application No.

10/635,081

Applicant(s)

ARGENTIERI, THOMAS M.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment filed February 18, 2005.
2. ☒ The allowed claim(s) is/are 14-22, now renumbered, 1-9.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>10-25-04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

COMMENTS

Applicant's Amendments filed October 25, 2004 and February 18, 2005 are acknowledged. Claims 1-13 are canceled. New claims 14-22 are presented and represent all of the claims now under consideration.

An Information Disclosure Statement filed October 25, 2004 is acknowledged and has been reviewed.

A new Abstract is noted.

In the last Office Action the disclosure was objected to because it was unclear whether Applicant intended to be limited to gastric motility or gastrointestinal motility.

Following the cancellation of claims directed to gastric motility and the introduction of new claims drawn to gastrointestinal motility, the objection of record is withdrawn. Support for "gastrointestinal motility" is provided in the specification on pages 11 and 12.

Claims 1-6 were rejected under 35 U.S.C. 112, first paragraph, in the last Office Action as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims were directed to the treatment or inhibition of hyperactive gastric motility comprising administering a compound of the formula of instant claim 1. It was asserted the specification provides support only for the administration of retigabine, which is not a compound of instant formula 1, to relax bladder and ileum tissue.

Art Unit: 1614

Applicant argues one skilled in the art would know how to confirm that the compounds of the present invention are effective in treating hyperactive gastrointestinal motility as recited in the claims without undue experimentation. On page 19 of the specification, Applicant urges an *in vitro* model for evaluating the ability of compounds to inhibit guinea pig ileum tissue contractions induced by KCl or carbachol is shown. This type of model is recognized by those skilled in the art as being useful for evaluating a compound's ability to treat/inhibit gastrointestinal hypermotility as supported by the teachings of Hennig et al., Journal of Physiology, and Toja et al., Arzneimittelforschung.

Applicant's arguments are persuasive and the rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

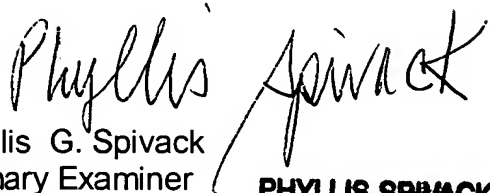
On line 1 under the heading "ABSTRACT OF THE DISCLOSURE", ", inhibiting, preventing and ameliorating" is deleted and -- or inhibiting -- is inserted therefor. On the first line under the formula "may be" is deleted and -- is -- is inserted therefor. On the second line under the formula ", for example," is deleted. On the third line under the formula, "abdominal pain associated with diarrhea," is deleted. On the fourth line under the formula, "or abdominal pain" is deleted.

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Mondays to Fridays from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at telephone number 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Phyllis G. Spivack
Primary Examiner
Art Unit 1614
**PHYLLIS SPIVACK
PRIMARY EXAMINER**

June 8 2005